

REMARKS

Claims 19-20 are amended herein. Claims 16-24 are currently under consideration.

The above-referenced Office action reiterates the rejection of independent claim 16 as obvious over the combination of Lee and Wratten because Wratten teaches a tubing system and Lee teaches a hemofilter in the desired molecular weight cutoff range. In responding to the Applicant's arguments, the Office action states that the circuit of Wratten is "capable of being modified" with the filter of Lee. Office action at page 6, line 3. The Office action then proceeds to state that this is not the test for obviousness. As then (correctly) recited in the Office action (page 6, lines 8-10), the test is not the possibility of the combination but what the combined teachings of the references would have suggested to those of ordinary skill in the art. After laying out the correct rule, the Office action proceeds to merely reiterate that the tubing of Wratten and the filter of Lee "can be combined". Office action at page 6, line 13, emphasis added.

The technical feasibility of making a combination is not a useful inquiry here. The obviousness/nonobviousness inquiry does not require that manufacturing the invention be seemingly impossible or even difficult. Certainly, one could substitute the filter of the present invention into the tubing system of Wratten, but only hindsight gained from learning of Applicant's invention provides the motivation to do so. The use of such hindsight is both unfair to the Applicants and improper. As stated by the Supreme Court in 1882, "Now that [the invention] has succeeded, it may seem very plain to any one that he could have done it as well. This is often the case with inventions of the greatest merit." *Loom v. Higgins* 105 U.S. 580 (1882).

The task at hand is saving patients from dangerous inflammatory-mediator related conditions, not configuring tubing and filters in a particular patterns. When one looks past the mechanical aspects of the system and adopts the proper medical point of view, it is clear that the prior art does not suggest the combination of Wratten and Lee. In addition to inherent unpredictability in the medical arts, therapy for conditions such as sepsis and acute organ failure are at best an emerging discipline, being a notoriously unmet medical need. Accordingly, a person of ordinary skill in the art might expect that exposing the ultrafiltrate

emanating from the large pores of the hemofilter specified by claim 16 to adsorbent material capable of binding toxins might result in the removal of critical blood components and adversely affect the patient. One of ordinary skill in the art would have also face a high level of uncertainty that the adsorbent would not foul and render the circuit wholly inoperative because neither Wratten nor Lee taught exposing adsorbent to high molecular weight blood components.

One important indicium of nonobviousness is “teaching away” from the claimed invention by the prior art. *In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). As to the specific question of teaching away, “A reference may be said to teach away when a person of ordinary skill, upon [examining] the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

Wratten and Lee teach away from each other. The office action newly concedes that Wratten teaches a hemofilter of small pore size. The purpose of the small pores is to selectively sieve cytokines. Because Wratten’s purpose is to eliminate cytokines, one of ordinary skill in the art would have no reason to look to Lee, which teaches the use of hemofilters with pores that remove albumin from the blood. See, e.g., claim 1 of Lee, which discloses molecular weight exclusion limits of 100,000 to 150,000 Da for the passage of 70,000 Da molecules. In contrast, filters of much lower porosity are suitable for Wratten’s purpose of removing cytokines from the blood, the largest being 26,000 Daltons. Furthermore, the purpose of Lee in removing larger molecules, which have a molecular weight of about 70,000 Daltons (see, e.g., Lee, claim 1), would be frustrated by substituting the filters of Wratten, which are designed for the removal of molecules of 26,000 Da or less, because these larger molecules of about 70,000 Da would not pass through such filters and thus would not be removed.

Wratten did not contemplate removing molecules of about 70,000 Da. As stated in Lee, at col. 9, ll. 12-33, due to both risk to the patient and expense, the practice in the art was to limit the pore size in order to exclude albumin (i.e., retain it in the blood). In contrast, Lee makes provision for replacing the lost albumin. Lee, at col. 9, ll. 31-32 (“Any risk of albumin loss will be offset by albumin replacement...”). Because the Wratten and Lee references teach contradictory medical approaches, they cannot be combined to reject the

pending claims for obviousness. The two references are medically incompatible, even if their plumbing is not.

Applicants submit that the dependent claims are patentable for at least the same reasons. Dependent claim 19 is currently amended to correct an obvious error and claim 20 is currently amended to clarify the function of the waste container.

Applicant respectfully submits that, for at least the foregoing reasons, all claims pending in the application are allowable over the art of record. Early notice to that effect is respectfully solicited. Reconsideration of the application and issuance of a notice of allowance are respectfully requested. It is believed that a 3 month extension of time is required, but Applicant hereby petitions for and requests that any other extension or other fee required for timely consideration of this application be applied and charged to Deposit Account No. 19-4972. The Examiner is requested to telephone the undersigned if any matters remain outstanding so that they may be resolved expeditiously.

Respectfully submitted,

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